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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,801	08/10/2000	Jennifer L. Mitcham	210121.462C4	6804

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

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23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/636,801	MITCHAM ET AL.	
	Examiner	Art Unit	
	Mary K Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-8,13-20,22,25-68 and 71-81* is/are pending in the application.

4a) Of the above claim(s) *3-8,13-17,19,22,25-36,41-68,71 and 72* is/are withdrawn from consideration.

5)☒ Claim(s) *73-81* is/are allowed.

6)☒ Claim(s) *18,20,22,28 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *3-8,13-20,22,25-68 and 71-81* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 3-8, 13-20, 22, 25-68, 71-81 are pending in this application. Claims 73-81 are allowed. Claims 3-8, 13-20, 22, 25-68, 71-72 stand withdrawn from consideration as being drawn to nonelected inventions. The petition to revive this application was granted, and the amendment filed 1/6/03 has also been entered.

Claims 73-81 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 18, 20, 27, 28 and 37-40, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 18-20, 27, 28 and 37-40 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In accordance with the Official Gazette notice, *supra*, process claims 35-36, 41-62, which do not depend from or otherwise include all the limitations of the allowable product, HAVE NOT been rejoined.

Claims 3-8, 13-17, 19, 22, 25-34 and 63-68, 71 and 72 are drawn to differing products and/or methods for the use of differing products and are NOT rejoined. These should be CANCELED by Applicant.

Claims 73-81 are drawn to an allowable product which originally fell in Group I in the Restriction Requirement mailed 4/6/01. This requirement identified Groups IX and XV as being methods of using the product of Group I.

In the Restriction Requirement mailed 4/6/01, it was clearly set forth that claims 18, 20, 27 and 28 read upon multiple independent and distinct inventions, and that the claims of Group IX and XV would only be examined to the extent they read upon a use of a polypeptide.

The rejoined claims must be amended to either depend from or otherwise include all the limitations of the allowable product, AND recite the allowed elected polypeptide sequence, SEQ ID NO: 392.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 20, 27, 28, and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 (CAFC 1988). The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below which leads to the determination that the above claims lack enablement due to undue experimentation being required to make and use the invention.

For enablement purposes, the experimentation which is necessary must be directed to the requirements under 35 USC 112, first paragraph, as summarized in the MPEP in 2162 which states that "the patentee must disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention." Thus, both making the invention must be enabled as well as a use thereof. The MPEP further summarizes these requirements in section 2164.01 in the "Test of Enablement" via stating that "Accordingly, even though the statute does not use the term 'undue experimentation,' it has been interpreted that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation." The MPEP further states in section 2164.01 that "The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." Further, "The test of enablement is not

whether any experimentation is necessary, but whether if experimentation is necessary it is undue." The MPEP then summarizes the below factors for the determination of the enablement requirement in 2164.01(a) as also set forth above as the so called Forman Factors. In the MPEP at section 2164.01(b), third paragraph, a key issue that can arise in the biotechnical area is the availability of starting materials to make the invention, especially when such availability is present "only after extensive screening." The MPEP at section 2164.01(c) further summarizes that requirement of a use for the claimed invention is included either as recited or based on knowledge of similar inventions, described as exemplified in relationship to compounds. Lastly, it is acknowledged that the specification does not need to disclose what is well known to those skilled in the art as described in the MPEP at section 2164.05(a), 6th paragraph.

The MPEP at 2164.04 requires that it is necessary to firstly construe the claims before any analysis of enablement can occur. Thusly the above rejected claims 18 and 37 are construed to be directed to the use of a polypeptide of SEQ: 392, or the following variants: a polypeptide comprising at least an immunogenic portion, or a variant thereof that differs in one or more substitutions, deletions, additions, and/or insertions such that the ability of the variant to react with antigen specific antisera is not substantially diminished, that is encoded by a polynucleotide of SEQ 391, or a complement of SEQ: 391. This polypeptide is construed as being prepared via host cell culturing wherein the host cell contains a vector which in turn contains a polynucleotide made up of normally found nucleotides which encode the polypeptide of SEQ ID NO: 392 via the translation of normally occurring triplet codons therein into said polypeptide.

Given the above summaries, it is appropriate to turn to consideration of the factors determinative of enablement regarding whether undue experimentation is required to enable the claimed invention.

The eight factors are summarized below regarding supporting the above rejection.

(1) – the quantity of experimentation necessary-

There are an enormous number of polynucleotides, vectors, and host cells to be experimentally tested in order to make a useful polypeptide of SEQ ID NO: 392. Regarding the polynucleotides to be tested, the art recognizes that for each amino acid in the polypeptide of SEQ:392 that there are degenerate codons available as shown in the well known Biochemistry textbook by Lehninger as in Table 31-5 on page 718. Counting the number of codons results in

observing that 5 of the normal amino acids may each be encoded by one of 4 three nucleotide codon options. For 9 of the normal amino acids, 2 such three nucleotide codon options are available. For 3 amino acids, 6 such codon options are available. For 1 amino acid, 3 such codons are utilized. For 2 amino acids, only one such codon is available. An average of the number of codons per amino acid may be approximated via an averaging of the above codon usage as being three available codons for an average amino acid. Without specifying the length of SEQ 391, it may be reasonably approximated that SEQ ID NO: 392 is a polypeptide which falls within the range of polypeptides with sizes as shown in the well known Biochemistry textbook by Lehninger as in Table 3-2 on page 57. A median polypeptide contains 550-800 amino acids. Choosing conservatively, a median polypeptide thus contains 500+ amino acids. Therefore, an estimate of the number of potential polynucleotides encoding SEQ ID NO: 392 of 500 amino acids would be that calculated at 3 raised to the 500^{th} power. This further calculates to approximately 10^{240} possible polynucleotides to evaluate or experimentally test to find those useable in making a useful polypeptide of SEQ 392, or a polypeptide meeting the limits of the genus of polypeptides in claims 18 or 37. Thus, there is an enormous number of polynucleotides to to experimentally test to find any that encode the polypeptide of SEQ 392 or its variants which are useful. The art of polypeptide usage in Biotechnology utilizes polypeptides via some type of enzymatic activity or binding activity. Claim 18 lacks citation of any such usefulness or activity limitation. Thus, another experimentation requirement regarded to enable the use of the instantly claimed methods is the determination of a useful activity for SEQ 392. The file history indicates that a polypeptide of exactly SEQ ID NO: 392 is useful in an antibody binding assay for diagnosing ovarian cancer. An antibody assay is strongly dependent on the three dimensional structure of the polypeptide. In the well known Biochemistry textbook by Lehninger at pages 58-62, not only is the vast diversity of protein polypeptides set forth regarding functionality, such as enzymatic function, but that each protein has a characteristic three-dimensional shape referred to as its conformation. The claims have not disclosed what function to test which alone relegates the experimentation to undue experimentation regarding a lack of any indication of what experimental test or assay is to be performed. This experimental search for a test is further complicated by a lack of any guidance regarding what single, or even a subset of polynucleotides out of the 10^{240} should be tested. These considerations are supportive of a determination of

undue experimentation to find a starting material polynucleotide to be placed in a vector and in turn a host cell for culturing, for production of a polypeptide to be used as claimed.

Turning to the question of what host cell is to be utilized in producing the polypeptide, it is well known that a myriad of thousands of cell types are known to Biotechnology. It is acknowledged that some of these known cell types are more commonly utilized for host cell culturing as described in the specification. Even such commonly utilized host cells number into the hundreds. In USP 5,082,767, Hatfield et al., the expression of polynucleotides in host cells of various types is described in column 1 lines 1-49. Even though such expression practices are frequently carried out, Hatfield et al describe another major problem in this area in column 1 lines 50-65, wherein a protein (or polypeptide) is produced in recoverable quantities, but is inactive. As discussed above, some type of activity is required for the polypeptide of SEQ: 392 to be used in the claimed methods. A solution is described in Hatfield et al in column 1 lines 61-65 as elusive and is apparently related to an unpredictability in proper protein folding during expression. In column 1 line 66 through column 2 line 59, various codon usage and context effects are described as problematic. In column 2 lines 53-59 the predictive value of statistical rules for preferred nucleotides adjacent to codons is described as relatively low. Hatfield et al go on to analyze codon pair usage frequencies wherein optimization of codon pair usage is then derived for determining polynucleotides which encode a protein or polypeptide in order to achieve an active polypeptide when made via a host cell culture such as described herein. This process, however, is complex and requires very specific host cell and polypeptide correspondence in order to perform the analysis to then make a useful and active protein. It is noted that the instant disclosure lacks any codon pair frequency analysis description for even a single host cell type. The Hatfield et al disclosure is a single procedural description which still lacks indication of how someone of skill in the art would find an activity assay to utilize for a polypeptide of SEQ: 392 to determine a predictable activity on which to base the codon usage analysis as disclosed therein. Thus, there would be no predictability as to what to direct a codon pair usage determination to as set forth in Hatfield et al. for the making of an active polypeptide. It is also pointed out that Hatfield et al. is a single disclosure and as such is not a well known practice for enabling the instant invention, and thus not available to applicant on this basis. Another disclosure of unpredictability in the art of codon usage is that of Nagata et al. (BBRC

261: 445-451 (1999)) wherein obstacles are summarized for the expression of genes in host mammalian cells on page 445, first paragraph after the abstract. Nagata et al. further describes an indication that codon study to clarify codon usage as related to polypeptide expression is known on page 445, second column lines 31-34. Nagata et al. was published years after issuance of the above cited Hatfield et al patent, and additionally documents the Hatfield disclosure as not being well known. Applicants cannot rely on a procedure in Hatfield et al as well known to assist in enabling the methods of claim 18 or 37.

Applicant may argue that inoperative subject matter is permitted in a claim and that generic polynucleotides what contain codons corresponding to encoding SEQ 392 which are inoperative are thus permitted within the scope of the claim. Consideration, however, of the MPEP at section 2164.08(b) regarding inoperative embodiments reveals that the standard is whether a skilled person could determine which embodiments, that were conceived, but not yet made, would be inoperative or operative with no more effort than is usually required in the art. This argument, however, would not be persuasive as some type of operativeness test would reasonably be required in order to make this determination. As discussed above, the myriad of possible testing for active polypeptides reasonably would require undue experimentation itself. Normally in the art, a specific test would be required for polypeptide activity assessment even if cultured as described. Such a test is not apparent for assessment of operative vs inoperative polynucleotides and host cells for preparation of a useful SEQ 392 polypeptide.

This, in summary, the above described unpredictability for polynucleotide testing, or even what test to perform as well as host cell selection with corresponding codon, codon pair and/or codon context practice is supported by the number into enormous possibilities. No instant guidance to reasonable narrow the required experimentation leads to a determination of undue experimentation being required for both polynucleotide selection, and host cell selection that would result in an active and therefor useful polypeptide of SEQ: 392 or variant thereof.

(2) – the amount or direction presented-

None other than the above described general knowledge in the art, which still leaves undue experimentation for enabling the instant invention.

(3)- the presence or absence of working examples-

No working examples have been presented to guide or enable the claimed polypeptides or methods of their use.

(4)- the nature of the invention-

The invention is complex as there is no guidance as to which activity, out of myriads possible to test for usefulness of SEQ ID NO: 392 once prepared. Even testing of polypeptide activity is generally a detailed process.

(5)- the state of the prior art-

Although many polypeptides have been cloned and expressed in culture, the Hatfield et al. summary indicates that the cultural expression of an active polypeptide is elusive and subject to many complex factors.

(6)- the relative skill of those in the art-

The cultural expression of polynucleotides in vectors in host cells to make a polypeptide is generally performed by graduate level or even more highly skilled individuals and is subject to numerous complex considerations for successful results. Even with this skill level, an unsuccessful result is frequently obtained, as noted above by Hatfield et al.

(7)- the predictability or unpredictability of the art-

The factors for making a useful and thus enabled polypeptide are elusive and unpredictable for a polypeptide wherein the polynucleotides which encode it for any host must be determined as described above.

(8)- the breadth of the claims-

The claims are directed to encompass polypeptides of a particular sequence, or encoded by a corresponding polynucleotide, or variants, substitutions, deletions or insertions therein. This is extremely broad regarding polynucleotides, vectors, and host cells that may be implemented in order to carry out the invention. As discussed above, the claim lacks any specificity as to what polynucleotides, vectors or host cells within this wide breadth of claim practice would be useable to result in the cultural making of an active polypeptide for use in the claimed methods.

Thus, in conclusion, the above rejected claims lack enablement due to undue experimentation required to practice the claimed methods.

Claims 18, 20, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The claims are drawn to methods of inhibiting the development of ovarian cancer by the administration of a polypeptide of SEQ ID NO: 392, or some unspecified uncharacterized derivative thereof. The specification does not disclose any data or experiments showing that the administration of SEQ: 392, or any of its sub-peptides, variants or derivatives, have any effect on the development of breast or ovarian cancer, nor does the specification disclose any information or data supporting that administration of SEQ: 392 has any effect on the course of breast or ovarian cancer. A vast multitude of polypeptides are encompassed by the claims as discussed above. No specific activity of the O8E protein is disclosed, nor is there a discussion of what portions of the protein are required for activity, or usefulness in preventing cancer. At no point are the in vivo properties of the O8E protein discussed such that one of skill in the art would be able to practice the above recited methods without undue experimentation. While working examples are not, per se, required, the specification must provide ample guidance for one of skill in the art to practice the invention. The O8E protein appears to be completely novel such that there is no body of art to rely on for enabling information and data. In the specification, polyclonal antibodies to SEQ NO: 392 were used for immunohistochemistry testing using ovarian cancer tissue samples (specification, p 5) however only 1 out of 6 samples was positive for an O8E antibody epitope. Examples 6 and 7 of the specification detail a FACS sorting analysis of a breast cancer cell line, a positive control cell line expressing O8E, and "MB415" cells, which are not identified. Presumably this is a negative control cell line, but its characteristics are not disclosed. No conclusions are drawn between the results of this assay on established cell lines, and any clinically relevant samples. While one type of breast cancer cell line may be positive for O8E expression, an immortalized cell line does not completely mimic the behaviour of a cell in vivo. As many types of ovarian cancer, and breast cancer (ductal, lobular carcinoma, mucinous carcinoma etc.) exist, clearly more testing would need to occur to determine whether or not the O8E antigen is useful in the detection of those cancers, let alone the treatment, inhibition or prevention thereof.

The art of cancer therapy recognizes that not all "cancer" antigens are useful in the treatment, prevention or alleviation of cancers. For example, Gillespie et al. (1998, PTO-1449) discusses how MAGE antigens were also found in normal tissue, leading to questions about previous assumptions of MAGE's role in carcinogenesis. Bookman (1998 PTO-1449) discusses the future of biological therapies of cancer, and details the great amounts of research necessary before a biological reagent such as an antibody or polypeptide can be used. Given the disclosure of the specification, one of ordinary skill in the art would have to perform additional tests to determine whether O8E is an antigen that is diagnostic for ovarian cancer or breast cancer, or whether the O8E protein would have an effects when administered in vivo. These additional tests require inventive skill and direction and therefore would require undue experimentation on the part of the practitioner.

Claims 18, 20, 27 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

Claim 18 recites that the portion or variant, or derivative of SEQ: 392 is able to bind an antibody with specificity to the polypeptide encoded by SEQ: 391, which is SEQ ID NO: 392. The specification, as filed, does not identify which portions of the polypeptide of SEQ ID NO: 392 would be likely to have antigenic sites such that they could bind to an antibody specific for SEQ ID NO: 392. The specification does not provide such an antibody that is specific to SEQ ID NO: 392. The identification of antigenic sites in a polypeptide sequence is not 100% predictable, nor is it clear that any particular predicted antigenic site would bind to an antibody specific to the whole polypeptide sequence. While working examples are not, per se, required in the specification, the disclosure must provide enough information for one of skill in the art to be able to practice the invention as it is now claimed, without undue experimentation. While the skill in the art of immunology and peptide science is high, the identification of antigenicity and binding to antibodies is unpredictable, and one of ordinary skill in the art would be required to perform undue experimentation on the predicted polypeptide sequence to identify polypeptides

having at least 20 contiguous amino acids, and which also bind to an antibody specific for the whole polypeptide.

Claims 18, 20, 27, 28 and 37-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 392 which corresponds to the "b form" of a protein designated O8E in the specification. The claims are directed to encompass immunogenic portions, immunogenic variants thereof, mutated sequences, allelic variants, substitutions, deletions, insertions, and additions to SEQ 392, and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 392, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The protein or nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

The specification does not set forth any of these definitions for other polypeptides which fall within the scope of the claims. An applicant may also show written description of an

invention by combining a partial structure, physical properties, or chemical characteristics with a known or disclosed specific function. However, no specific function or activity had been ascribed to any one elected sequence in the specification, as filed.

The written description requirement for any claim drawn to a genus can be met through sufficient description of a representative number of species within the genus. The broadest claim for the elected polypeptide is a separate genus. The specification, as filed, only discloses the single species of SEQ: 392, which is not sufficient to support the assertion that Applicant was in possession of the entire genus being claimed.

Therefore, claims drawn to purified polypeptides comprising SEQ: 392, but not the full breadth of the claims, would meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Conclusion

Claims 73-81 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD can be reached on (571) 272 0718. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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2/25/05